

**U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE**

AUDIT REPORT M&O-ARP-99-009

OF THE

**CIVILIAN RADIOACTIVE WASTE MANAGEMENT SYSTEM
MANAGEMENT AND OPERATING CONTRACTOR**

AT

LAS VEGAS, NEVADA

OCTOBER 11-15, 1999

Prepared by: _____ **Date:** _____

**Daniel A. Klimas
Audit Team Leader
Office of Quality Assurance**

Approved by: _____ **Date:** _____

**Robert W. Clark
Acting Director
Office of Quality Assurance**

1.0 EXECUTIVE SUMMARY

This performance-based Quality Assurance (QA) audit was conducted on the processes and activities related to the Integrated Site Model (ISM) Process Model Report (PMR) at the Civilian Radioactive Waste Management System Management and Operating Contractor (CRWMS M&O) Offices in Las Vegas, Nevada, October 11-15, 1999. The purpose of the audit was to evaluate the effectiveness of the Analysis and Model Report (AMR) process and quality of the resultant end product the ISM PMR. The ISM PMR will provide a summary and synthesis of the three AMRs: Geologic Framework Model, Mineralogic Model, and Rock Properties Model. The ISM will provide an updated three dimensional representation of selected stratigraphic layers and structures, mineralogical abundances, and rock properties.

The audit team determined that the CRWMS M&O has effectively implemented critical process steps relative to the ISM activities evaluated with the following exceptions: deficiencies were identified in the areas of Software, Level 3 Change Control, and the Control of the Electronic Management of Data (see Section 5.0 for specific details). Based upon reviews of in-process documentation, interviews of personnel, and examination of procedure processes, the audit team determined that ISM activities being conducted at the time of the audit meet Office of Civilian Radioactive Waste Management (OCRWM) QA program requirements. It should be noted that while the process activities were evaluated to the extent possible relative to the ISM PMR, the supporting AMRs and PMR were in draft form.

The audit team identified three deficient conditions. Deficiency Report (DR) LVMO-00-D-011 addresses that the AMRs were developed without following the requirements of AP-3.4Q, Revision 1, ICN 0, "Level 3 Change Control." DR LVMO-00-D-012 addresses the fact that unqualified software was used in the development of AMRs. A deficient condition regarding the Control of Electronic Management of Data was identified and addressed on a Deficiency Identification Referral (DIR) form and added to the extent of condition of a previously written DR, LVMO-98-D-055 for the same condition. Additionally, eight recommendations were provided to the CRWMS M&O for administrative and process improvements. Details of the deficient conditions and recommendations are presented in Section 5.0 and 6.0 respectively.

2.0 SCOPE

The audit was conducted to evaluate the effectiveness of the AMR process for the development of the ISM PMR. The audit team evaluated documented activities that constitute scientific, engineering and performance assessment analysis and models pertaining to the ISM. Related draft AMRs were examined to determine the effectiveness of the reports in providing evidence to support the ISM and to characterize the geology of the proposed high-level radioactive waste repository site at Yucca Mountain.

The ISM AMRs will support the Total System Performance Assessment (TSPA) on the subject and serve as an important reference to the License Application. The following processes and products were examined as part of this audit:

- Work Planning Summary for “Integrated Site Model Process Model Report,” DI WPP-MGR-MD-000006, Rev. 00.
- The analysis and model process from planning through submittal of data and models to the Technical Data Management System (TDMS).
- Draft, “Mineralogical Model (MM3.0)” Analyses Model Report, Document Identifier (DI), MDL-NBS-GS-000003, Rev 00B.
- Draft, “Geologic Framework Model (GFM3.1)” Analyses Model Report, DI MDL-NBS-GS-000002 Rev. 00C.
- Draft, “Rock Properties Model (RPM3.1)” Analyses Model Report, DI MDL-NBS-GS-000004, Rev 00B.
- Draft, “Integrated Site Model Process Model Report,” Annotated Outline.
- Draft, “Integrated Site Model Process Model Report,” DI TDR-NBS-GS-000002, Rev 00A.
- Data Qualification Plan, DI TDP-NBS-GS-000001, Rev 0, “Borehole Stratigraphic Contacts Data.”
- Data Qualification Plan, DI TDP-NBS-GS-000002, Rev 1, “Drill Core Samples, Lithostratigraphic Contacts, Core Photos and Downhill Video.”
- Data Qualification Plan, DI, TDP-NBS-GS-000003, Rev 0, “Calculated Porosity Logs and Related Composite Geophysical Logs.”
- Data Qualification Plan “Logs of Geophysical Recording Runs” (developed per procedure YAP-SIII.1Q, no DI number required).

The audit team conducted personnel interviews and examined documentation in accordance with the approved audit plan to evaluate the adequacy and effectiveness of the critical process steps for the development of the AMRs that support the ISM PMR.

2.1 Process Steps/Products/Documentation

The performance-based evaluation of process effectiveness was based upon the following:

1. Satisfactory completion of the critical process steps
2. Documentation that substantiates the quality and traceability of data
3. Performance of trained and qualified personnel; and
4. Implementation of applicable QA program elements.

The following critical process steps were considered during the evaluations of the AMR process:

1. Planning
2. Development and documentation of AMRs/PMR
3. Validation of models
4. Use of software or models
5. Documentation check and review
6. Approvals
7. Editorial corrections
8. Analysis or Model revision or change
9. Submittal of data and models to the TDMS.

- 2.2 The audit included a technical evaluation of the adequacy and effectiveness of the AMR/PMR process. Details of the technical evaluation are documented in Section 5.4 of this report.

3.0 **AUDIT TEAM MEMBERS/OBSERVERS**

Daniel A. Klimas, Audit Team Leader, Office of Quality Assurance (OQA)
Kristi A. Hodges, Auditor, OQA
Steve D. Harris, Auditor, OQA
Victor J. Barish, Auditor, OQA
John R. Doyle, Auditor, OQA
Robert P. Hasson, Auditor, OQA
Keith M. Kersch, Technical Specialist, Science Applications International Corporation

There were four observers present during the audit:

Ted Carter, Nuclear Regulatory Commission (NRC) Observer, Washington, D.C.
Bill Dam, NRC Observer, Washington D.C.
Bruce Mabrito, NRC Observer, San Antonio, Texas
Gerry Stirewalt, NRC Observer, Washington D.C.

4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

A pre-audit meeting was conducted at the CRWMS M&O Offices, Las Vegas, Nevada, on October 11, 1999. Daily debriefings were held to apprise the CRWMS M&O management and staff of the progress of the audit and of any potential conditions adverse to quality. A post-audit meeting was conducted at the CRWMS M&O Offices, Las Vegas, Nevada, on October 15, 1999.

Personnel contacted during the audit, including those that attended the pre-audit and post-audit meetings, are listed in Attachment 1, "Personnel Contacted During the Audit."

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that critical process steps applicable to the AMR/PMR process were effectively implemented; however, three deficient conditions were identified with procedure implementation: Software Management, Level 3 Change Control, and Control of the Electronic Management of Data. Details of these deficient conditions adverse to quality are presented in Section 5.5.2 of this report. The last deficient condition was referred to an existing deficient report, as described in Section 5.2.2. Eight recommendations are provided in Section 6.0.

During the audit, corrective action was evaluated with relation to the significant deficiencies documented in existing Corrective Action Reports (CAR) that could impact the ISM AMR/PMR process. The following is a status of the CARs as a result of the evaluation conducted during the audit:

CAR LVMO-99-C-001

Based on reviews during the ISM audit, this CAR will remain open.

The assessment of procedures AP-3.10Q, Revision 1, ICN 1, "Analysis and Models," and AP-3.15Q, Revision 0, ICN 1, "Managing Technical Product Inputs," was found to be satisfactory to date in addressing the traceability and technical adequacy of data. There were a couple of recommendations regarding the checking process; however, there is no adverse impact on the ISM AMRs/PMR based on these recommendations to this point. Additionally, the new Data Input Reference Sheet system will need to be further evaluated once electronically operational.

There is a concern for other PMRs that may be affected by a commitment in the CAR response. The PMRs are required to list all documents that were used/

considered/reviewed in preparing the AMRs. Authors are required to complete a form for each bibliographic entry and provide a justification for using or not using these documents. The latest CAR-001 response should be evaluated with respect to this issue.

OQA verification will continue through the PMR audits. Two PMRs (Biosphere and Waste Package) are scheduled for November 1999.

CAR LVMO-98-C-002

Based on reviews during the ISM audit, this CAR will remain open.

AP-3.15Q checklists continue to be completed; however, some problems are still occurring during the completion of the checklists with respect to consistency and accuracy. Positive steps are being taken to address these issues.

The verification will continue through the OQA Phase 3 verification activities. During Phase 3, the OQA Verification Team will verify remaining open items from the CAR Management Plan commitments.

CAR LVMO-98-C-006

Based on reviews during the ISM audit, this CAR will remain open.

CAR-006 involved identifying software codes that will be used for SR/LA and determining/assuring their qualification status. The CAR-006 software reverification effort identified previously qualified software codes and subjected them to reverification in accordance with current QARD requirements. The reverification effort has been completed and resulted in confirming the qualified status of 89 codes and rejecting an additional 35 codes. The codes that were not successfully reverified were initiated for qualification in accordance with AP-SI.1Q, Revision 1, Revision 1, ICN 0, "Software Management."

CAR-006 corrective action resulted in establishing a centralized process for qualifying and controlling project software codes that are subject to the requirements of the QARD. This process was established with the issuance of AP-SI.1Q, Revision 1. The OQA verification of CAR-006 is in its final stages, with acceptable results for the reverification effort and initial implementation of AP-SI.1Q. Although revision 2 and 3 are in progress to clarify areas that, in part, came out of Phase 2 of the OQA CAR Management Plan, revision of this procedure is not necessary to meet CAR-006 corrective action commitments.

It should be clearly understood that CAR-006 does not require that all software codes be qualified. There are software codes that have been used for quality-

affecting work that have yet to be qualified; i.e., those currently being processed per AP-SI.1Q and/or legacy software that may be identified as part of the CAR-002 data reverification effort. The process established in AP-3.15Q precludes qualification of data until the qualification of associated software is accomplished and confirmed; therefore, data sets will not be qualified (TBVs will not be lifted) until all software codes associated with that data set are qualified/verified.

The verification will continue through the OQA Phase 3 verification activities and evaluation during AMR/PMR audits.

CAR LVMO-98-C-010

Based on reviews during the ISM audit, this CAR will remain open.

The remaining action required for closure of CAR-010 include generation of "family trees," which demonstrate model inputs/outputs and the relationships between the AMRs and PMRs. In addition, an evaluation of effectiveness of AP-3.10Q implementation was to be performed. Based upon this ISM audit, implementation of AP-3.10Q is satisfactory; however, there are issues regarding the accuracy of the "family trees" that have been provided to meet CAR-010 commitments. The model database maintained by Performance Assessment was corrected during this audit to reflect accurate model inputs/outputs and software for the ISM; however, the family tree still needs to be corrected. Based on discussion, an alternate method by which to demonstrate the family tree is being considered. The resolution of this issue will continue beyond this audit.

The verification will continue through the OQA Phase 3 verification activities.

5.2 Stop Work or Immediate Corrective Actions Taken

There were no Stop Work Orders or immediate corrective actions taken as a result of the audit.

5.3 QA Program Activities

Attachment 2, "Summary Table of Audit Results" provides results for each critical process step evaluated. Details of the audit, including the objective evidence reviewed are documented in the audit checklist. The checklist is maintained as a QA Record.

5.4 Technical Audit Activities

The ISM is a PMR (TDR-NBS-GS-000002) that summarizes three AMRs. These

are the Geological Framework Model (GFM 3.1) AMR (MDL-NBS-GS-000002), the Rock Properties Model (RPM 3.1) Report (MDL-NBS-GS-000004), and the Mineralogical (MM 3.0) Model Analysis Model Report (MDL-NBS-GS-000003). These reports were in various stages of completion, and none had been finalized. In examining the work in progress, the audit team reviewed the draft reports, laboratory scientific notebooks, pertinent records, and conducted interviews of the principal investigators and other key personnel.

The principal procedure governing the preparation of AMRs is AP 3.10Q. The draft reports were not available during the planning phases, so checklists were initially prepared with a strong focus toward examining procedural processes. Draft reports were made available during the week before the audit. The audit team examined draft versions of the four reports and used the information in these reports, along with the checklists, to structure the nature of interviews of key personnel.

The AMRs were in the process of being reviewed and revised so it was not possible to examine or assess the final products. The checking process associated with preparation of the reports was examined and found to be very thorough. The dedication of the checkers in helping develop quality technical products is to be commended. The audit team is confident that the final products will be reliable, and the organizations involved are knowledgeable with respect to the QA program.

The check copies produced for the AMRs were examined at great length by the checkers. The process of checking is not defined in formal procedures, but it is well controlled, uniform and organized. The audit team recommends that the use of the checker's checklist should be formalized, even though the checking process appears to be working well and is expected to contribute to production of quality products.

The principal computer software package is EARTHVISION, which is a three-dimensional modeling program, used to produce visualizations of the models. The AMR Lead demonstrated the capabilities of the software associated with the ISM during the audit. The AMRs were considered to be good technical products, and the process for developing the models is effective.

5.5 Summary of Conditions Adverse to Quality

The audit team identified three deficiencies during the audit, one which was addressed on a DIR form to an existing DR, LVMO-98-D-055 regarding QARD,

Supplement V, “Control of the Electronic Management of Data.” These deficiencies are discussed in detail in Section 5.5.2 below.

5.5.1 Corrective Action Request (CAR)

None.

5.5.2 Deficiency Reports (DR)

DR LVMO-00-D-011

AP-3.4Q, Paragraph 5.2, “Determine Scope of Technical Baseline Change,” 5.2.1, “Subject Matter Expert” states:

- a) Perform a preliminary impact analysis using applicable criteria from Attachment 6, “Guidelines for Review of Level 3 Technical Baseline Change Scope.”
- b) Ensure that reasonable alternatives were considered, and include the rationale that supports the decision selected in the preliminary impact analysis.
- c) Review document history to ensure that previously approved changes are considered (not required for initial issue).
- d) Attach explanatory documentation to the Technical Change Request (TCR) that includes a summary of technical impacts, interface impacts, and impacts on other documents.
- e) Add name, signature, and date.
- f) Submit the TCR package to the Responsible Manager for further processing in accordance with paragraphs 5.2.2 through 5.2.7.

Contrary to Section 5.2, TCRs for the “Rock Properties Model,” AMR, TCR # 31999-0087; “Mineralogical Model” AMR, TCR # T1999-0088; the “Geologic Framework Model” AMR, TCR # T1999-0133; and the “ISM PMR,” TCR # T1999-0216 were initiated and submitted to the Change Control Board that did not satisfy the requirements.

DR LVMO-00-D-012

AP-SI.1Q, Section 2.0, Paragraph 5, states, “Unqualified software must follow the steps outlined for either acquired, developed, or modified

software in accordance with Section 5.0 of this procedure before it can be used to support quality-affecting work.”

Contrary to the above requirement, the following software was not qualified prior to being used to support quality affecting work for the ISM: Wildsoft v. 1.65; QLA2/GES v. 1.0; Stratamodel v. 4.1.1; VARIO v. 1.16 and v. 1.20; and VARIOFIT v. 1.20.

SUPPLEMENT V DEFICIENCY (DIR TO DR LVMO-98-D-055)

Process Control Evaluation forms created to support ISM activities have been completed; however, they do not reflect adequate controls for implementation of QARD, Supplement V, “Control of the Electronic Management of Data.” The forms indicate that controls need to be applied to work activities; however, they identify that no procedure changes are required because the controls in place are adequate. The condition of lack of Supplement V controls is currently documented in DR, LVMO-98-D-055. A DIR form was written to add this deficiency to the DR extent of condition and will be part of the corrective actions that need to be performed to resolve that deficiency.

5.5.3 Deficiency Corrected During the Audit (CDA)

A Natural Environment Program Operations (NEPO) memo, dated August 31, 1999, was issued to lift a “Global” To-Be-Verified (TBV) from the TDMS; however, the Data or Technical Information Checklist for reverification was not yet completed. Additionally, there is an unresolved question regarding the status/qualification of the software identified in the reverification checklist. It was further determined that the TBV had not been removed from the TDMS, so there was no quality impact. A letter from NEPO was issued to retract the August 31, 1999, TBV removal Memo. NEPO personnel performed a review and determined that there were no other DTNs with TBVs lifted prior to completion of the reverification checklist. NEPO personnel were provided with instruction with regards to the requirements. This was considered to be an isolated condition and was corrected during the audit.

6.0 RECOMMENDATIONS

1. The Project has consolidated the qualification of personnel under a single procedure (AP-2.2Q, Revision 0, “Establishment and Verification of Required Education and Experience of Personnel”). However, personnel supporting the various PMRs, including the ISM, have been qualified under superseded procedures; e.g., laboratory

- qualification procedures. Because AP-2.2Q requires the responsible manager to evaluate personnel qualifications, there should be a determination of whom the responsible manager is; i.e., the M&O/laboratory lead with administrative responsibility or the functional lead with responsibility for the work activity. If previous qualification documentation is to be relied upon as evidence of personnel qualification, the functional manager needs to assure that assigned personnel have the appropriate education and/or experience to perform the assigned tasks. This can be accomplished by revising qualification documentation to reflect current work activities or by a documented endorsement of the previous qualification documentation as being sufficient to meet current work activities. The CRWMS M&O should evaluate these two qualification issues and determine the appropriate actions to demonstrate personnel qualification with respect to current work activities.
2. The Data Qualification Plan, "Logs of Geophysical Record Runs," was developed in accordance with a previous procedure, YAP-SIII.1Q, Revision 3, "Qualification of Unqualified Data." The Data Qualification Plan should be revised in accordance with the current procedure requirements of AP-SIII.2Q, Revision 0, "Qualification of Unqualified Data and the Documentation of Rationale for Acceptance Data."
 3. Procedures QAP 6.2, Revision 4, "Document Review," AP-3.10Q, AP-2.14Q, Revision 0, "Review of Technical Products," and AP-SI.1Q, include requirements with respect to performing technical reviews. There is confusion and conflicting direction as to which procedures are applicable. The review process should be evaluated to be made as consistent as possible among procedures.
 4. Procedure 3.10Q is not clear in addressing independent technical reviews. It is not clear as to the justification by the AMR/PMR Leads to bypass the AP-2.14Q technical review of AMRs. Additionally, if the checker is the function for independent technical review, it is recommended that the procedure clearly state this.
 5. In the Mineralogy Model AMR, mineral abundance is calculated using an equation referenced in the AMR. The justification should be provided in the AMR and Scientific Notebook as to why this equation was used to further strengthen the selection.
 6. AP-SIII.1Q, Revision 0, "Scientific Notebooks," requires a technical review on the notebook when it supports a deliverable. AP-3.10Q also has review requirements. The scientific notebook review should be completed prior to issuing the AMRs to ensure steps are met in both procedures for review on the notebooks.
 7. The AP-SI.1Q definition for software routine can be a stand-alone code, unchanged from the supplier. However, the text expects the source code to be available. The

procedure should be changed to permit use of vendor supplied software unchanged by the user.

8. There is a Guidance List that was developed by the NEPO to assist the Responsible Manager and personnel in implementing the AP-3.10Q process. This is a step-by-step guide to implement the AP-3.10Q process with a cross-reference to other applicable procedure requirements. This guidance list should be distributed to other organizations developing AMRs to assist in assuring full implementation of procedure requirements.

7.0 LIST OF ATTACHMENTS

Attachment 1, Personnel Contacted During the Audit
Attachment 2, Summary Table of Audit Results

ATTACHMENT 1

PERSONNEL CONTACTED

Name	Organization/Title	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
Andrews, Bob	M&O/Duke, PA	X	X	X
Bates, Greg	M&O/MK, Chief of Survey		X	
Biggar, Norma	M&O/URSGWCFS	X	X	X
Boyles, Alice	M&O/SEA Technical Documentation Specialist		X	
Burningham, Andrew	M&O/TRW, NEPO QA Liaison	X	X	
Calloway, David	M&O/Operations MGR	X	X	
Carey, J. William	LANL/AMR Lead		X	
Carlisle, Greg	M&O/TRW		X	
Clayton, Robb	M&O/URSGWCFS, GFM AMR Lead/ISM PI	X	X	X
Eshleman, Mike	OQA/QATSS, Sr. QA Specialist	X	X	X
Frazier, Robert	M&O/SAIC, Analytical Support Specialist		X	
Hayes, Larry	M&O/TRW, NEPO Manager		X	
Hays, Tom	NEPO/Functional Design, Engineer	X	X	X
Hill, Don	M&O/Duke, NEPO, Reg. Specialist		X	X
Houston, C. J.	M&O/TRW, NEPO, System Analyst	X	X	
Hoxie, Dwight	USGS, Manager, Process Modeling & PA Support	X	X	X
Jenkins, Dan	M&O/Duke, Regulatory Compliance & Safety Supervisor	X	X	
Keith, Dale	M&O/TRW, Automated Technical Tracking Administrator		X	
Kemp, J.D.	M&O/URSGWCFS		X	
Lum, Clinton	M&O/SNL, ISM PRM Lead/Data Qualification Chairman		X	X
McGrath, Mike	M&O/TRW		X	
McNeish, Jerry	M&O/Duke, PA		X	
Myette, Tom	M&O/TRW, CCB Secretary		X	
Olson, David	M&O/URSGWCFS, Petrophysicist		X	
Pelletier, John	M&O/SNL, Technical Staff, NEPO	X	X	X
Peppers, Don	M&O/Volt		X	

Name	Organization/Title	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
Peters, John	M&O/MGR Engineering Services	X	X	X
Rael, Howard	M&O/SAIC, Senior Petrophysicist		X	
Rautman, Chris	M&O/SNL		X	
Reynolds, Tom	M&O/Project Geologist	X	X	X
Sanchez, Paul	M&O/SNL, NEPO Project Scientist	x	X	
Wilkins, Dan	M&O/AGM	X	X	X
Zeisloft, Jon	M&O/URSGWCFS, Project Scientist	X	X	X
Zelinski, William	M&O/URGSWCFS		X	
Zinkevich, Fred	M&O/TRW, RSO	X	X	

Legend:

AGM	Assistant General Manager
AMR	Analysis & Model Report
CCB	Change Control Board
FD	Fluor Daniel
GFM	Geologic Framework Model
M&O	Management and Operating Contractor
MGR	Monitored Geologic Repository
MK	Morrison-Knudsen
NEPO	Natural Environment Program Operations
ISM	Integrated Site Model
PA	Performance Assessment
PI	Principal Investigator
PRM	Process Model Report
QA	Quality Assurance
QATSS	Quality Assurance Technical Support Services
OQA	Office of Quality Assurance
RSO	Repository Systems Operation
SAIC	Science Applications International Corporation
SNL	Sandia National Laboratory
SEA	Science and Engineering Associates, Inc.
SNL	Sandia National Laboratories
TRW	TRW Environmental Safety Systems, Inc.
URSGWCFS	URS Greinier Woodward-Clyde Federal Services
USGS	U.S. Geological Survey

ATTACHMENT 2

SUMMARY OF TABLE OF AUDIT RESULTS

Process Steps	Details (Checklist)	Deficiencies	Recommendations	Process Effectiveness	Overall
Planning	p. 1-3		1, 8	SAT	SAT
Development and Documentation of AMRs/PMR	p. 4-17	LVMO-00-D-011	5	UNSAT	SAT
Validation of Models	p. 18-23		2	SAT	SAT
Use of Software or Models	p. 24-31	LVMO-00-D-012	7	UNSAT	SAT
Documentation Check and Review	p. 32-39	LVMO-00-D-011	3, 4, 6	UNSAT	SAT
Approvals	p. 39			SAT	SAT
Editorial Corrections	p. 40-42			SAT	SAT
Analysis or Model Revisions or Change	p. 43			SAT	SAT
Submittal of Data and Models to the TDMS	p. 44-45	LVMO-98-D-055		UNSAT	SAT
DELIVERABLES					
ISM PMR, Draft GFM AMR, Draft RP AMR, Draft MN AMR, Draft	p. 4-17			SAT	SAT
Analysis and Model (overall implementation)				SAT	SAT

Legend:

SAT	Satisfactory
UNSAT	Unsatisfactory